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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/742,785	12/20/00	CURATOLO	W PC10755AJTJ

HM12/1010

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EXAMINER	
FUBARA, B	
ART UNIT	PAPER NUMBER
1615	3

DATE MAILED: 10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/742,785	CURATOLO ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-155 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-155 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-155 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piergiorgio et al. (US 4,880,623).

Piergiorgio teaches a composition comprising nifedipine (an anti-hypertensive), polyethylene glycol, hydroxypropylmethyl cellulose and other excipients (abstract and example 2). Piergiorgio teaches that the bioavailability of the drug in the above composition is highly increased. However, Piergiorgio does not teach the drug concentration in the use environment after introduction of the composition in the use environment is 1.25 fold the equilibrium concentration of said drug in said environment. But one of ordinary skill in the art would know routine methods of determining that parameter. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Piergiorgio. One having ordinary skill in the art would have been motivated to prepare the composition of Piergiorgio where the drug displays increased bioavailability in the environment of use. Although, applicants say on page 6, lines 1 and 2 that Piergiorgio does not compare different drug forms, applicants failed to demonstrate that the instant composition displays a higher bioavailability than the composition of Piergiorgio. Examples 1-20 of the application are

directed to amorphous drug forms and there is no comparison between the amorphous form and crystalline forms.

3. Claims 1-155 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamichi et al. (US 5,456,923).

Nakamichi teaches compositions that comprise solid dispersions of drugs (abstract). The composition further comprises natural or synthetic polymer. The polymer is pH-dependent, pH independent or water-soluble. The polymers include hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, carboxymethylethylcellulose, cellulose acetate phthalate, hydroxypropylcellulose and hydroxypropylmethyl cellulose (column 2, lines 33-59). The drugs which can be used in the invention are antipyretic, analgesic and anti-inflammatory agents, anti-ulcer agents, coronary vasodilators, peripheral vasodilators, antibiotics, anti-spasmodic agents, anti-tussive and anti-asthmatic agents, bronchodilators, diuretics and muscle relaxants (column 3, line 50 to column 5 line 56). The preferred drugs in the invention of Nakamichi are non-heat labile drugs (column 3, line 51). Although, Nakamichi teaches increased bioavailability these drugs, the reference is silent on the concentration of the drug in the use environment following administration compared to the equilibrium concentration of the drug in said use environment. However, one of ordinary skill in the art would know routine methods of determining that parameter. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Nakamichi. One having ordinary skill in the art would have been motivated to prepare the composition of Nakamichi where the drug displays increased bioavailability in the environment of use. Although, applicants say on page 5, lines 4-11 say that Nakamichi teaches amorphous drug

forms, applicants failed to demonstrate that the instant composition displays a higher bioavailability than the composition of Nakamichi. Furthermore, examples 1-20 of the application are directed to amorphous drug forms and there is no comparison between the amorphous form and crystalline forms.

Specification

4. The disclosure is objected to because of the following informalities: Page 3, line 20 does not have the US Patent number listed.

Appropriate correction is required.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
October 5, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600